REMARKS

Claims 1-19 and 26-28 are pending in the application. Applicant thanks the Examiner for the kind allowance of Claims 1-12 and for stating that Claims 14 and 19 are allowable if rewritten to overcome the rejections under 35 U.S.C. 112 and to include all the limitations of the base claim and any intervening claims. However, for the present, Applicant respectfully declines the opportunity to rewrite these claims in independent form but reserves the right to do so at a future time.

Claim 16 has been amended to correct typographical errors. Figs. 3A, 3B, 3C, and 3D have been amended to conform with the specification and claims as requested by the Examiner. The specification has been amended to correct typographical errors and to conform with the claims. The amendments are supported in the specification, claims, and drawings. Thus, no new matter has been added.

Election/Restrictions

The Office Action states:

> "Applicant's election with traverse of Group I, Species 1 (Figures 1, 2, 3a, 14 and 15) in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the examiner has not set forth enough reasons for the election. This is not found persuasive because applicant merely sets for the legal arguments with spurious conclusory factual arguments that the species are not distinct. In addition, applicant has not admitted that the species are obvious variants as required in paragraph 9. Applicant should note that additional restriction requirements could have easily been made, for example, between claims positively reciting the hemostasis material and those not reciting such. Further, applicant is probably not aware that the examiner is accorded only 6.0 hours to do the entire first office action. This involves reading the application, analyzing the figures (22 sheets in the instant application), analyzing the claims, crafting a prior art search strategy, searching the claims, comparing the claims to the discovered prior art, deciding what claims are patentable, and preparing this office action. Accordingly, applicant's complaint that the restriction applied is unfair is not well-taken. ... The requirement is still deemed proper and is therefore made FINAL."

Applicant respectfully disagrees. Accordingly, Applicant has filed a Petition From Requirement For Restriction Under 37 CFR 1.144. A copy is attached for the Examiner's convenience (Tab A).

Drawings

The proposed drawing correction filed on June 9, 2003 was not approved. Specifically, the office action states that the "drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the features of claims 5 and 6, wherein the hydration chamber has a tapered portion in between two larger portions, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Since this subject matter is described in the original disclosure, applicant may submit drawings showing this feature." This objection is respectfully traversed.

The proposed drawing correction filed on June 9, 2003 was to merely change one number in Fig. 11 from "322" to "332" to conform with the specification. It is respectfully requested that the amendment to Fig. 11 filed on June 9, 2003 be approved and entered.

Figs. 3A, 3B, 3C, and 3D have been amended to include the features of Claims 5 and 6. However, it is pointed out that these features are also included in other figures such as Fig. 6, among others.

Thus, it is respectfully requested that this objection be withdrawn and the amendments to Figs. 11 and 3A-3D be approved and entered.

Specification

The specification is objected to as allegedly "failing to provide proper antecedent basis for the claimed subject matter." The office action states that there "does not appear to be a description of claims 5 and 6 in the specification or the drawings. However, since this subject matter was described in the original claims, applicant should submit an amendment to the specification and additional drawings." Applicant respectfully traverses this objection.

Claim 5 reads:

> "The system of Claim 1, wherein the hydration chamber has a first inner diameter, a second inner diameter, and a tapered portion between the first and second inner diameters for compressing the hemostasis promoting material."

Support for Claim 5 may be found in paragraph [0062] which states "the hydration chamber 112 includes a large inner diameter at a proximal end 132 and a smaller inner diameter distal end 134. The vent tube 126 is provided along the smaller inner diameter distal end 134 of the hydration chamber 112 distally of a tapered portion 136 of the hydration chamber."

Claim 6 reads:

> "The system of Claim 5, wherein the second inner diameter is substantially the same as an inner diameter of the introducer sheath."

The specification in paragraph [0062] has been amended to state that the "smaller inner diameter distal end 134 may be substantially the same as the inner diameter of the introducer sheath."

Thus, it is respectfully requested that this objection be withdrawn.

I. Status Of Claims

Claim 15 stands rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter applicant regards as the invention.

Claim 13 stands rejected under 35 U.S.C. § 102(e), as being allegedly anticipated by USP 6,162,192 hereinafter "Cragg '192".

Claims 26 and 28 stand rejected under 35 U.S.C. 102(e) as being allegedly anticipated by USP 6,071,301 hereinafter "Cragg '301".

Claims 16 and 17 stand rejected under 35 U.S.C. 103 (a) as being allegedly unpatentable over USP 1,578,517 hereinafter "Hein". Claims 16 and 17 also stand rejected under 35 U.S.C. 103 (a) as being allegedly unpatentable over USP 5,431,639 hereinafter "Shaw".

II. Discussion of Rejections

A. Rejection under §112

Claim 15 stands rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter applicant regards as the invention. Specifically, the office action states "Claim 15 is dependent on claim 13 but should be dependent on claim 14. Claim 15 will be examined as if it depends on claim 14."

Claim 15 has been amended to depend upon Claim 14. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

B. Rejections under 35 U.S.C. §102

1. Standard under 35 U.S.C. §102

According to M.P.E.P. §2136.02, "[f]or applications filed on or after November 29, 1999, if the applicant provides evidence that the application and prior art reference were ... subject to an obligation of assignment to the same person, ... any rejections under 35 U.S.C. 102(e)/103 based upon such a commonly owned reference should not be made or maintained." See also, MPEP §706.02(II).

2. Rejections under 35 U.S.C. §102 over Cragg '192

Claim 13 stands rejected under 35 U.S.C. § 102(e), as being allegedly anticipated by Cragg '192. This rejection is respectfully traversed. Cragg '192 and the present application, were, at the time the invention was made, owned by, or subject to an obligation of assignment to the same entity, Sub-Q, Inc. The assignment for Cragg '192 may be found in Reel 9371 Frame 0797 and the assignment for the present invention may be found in Reel 012613 Frame 0797. Accordingly, it is respectfully requested that this rejection be withdrawn.

3. Rejections under 35 U.S.C. §102 over Cragg '301

Claim 26 stands rejected under 35 U.S.C. 102(e) as being allegedly anticipated by Cragg '301. This rejection is respectfully traversed. Cragg '301 and the present application, were, at the time the invention was made, owned by, or subject to an obligation of assignment to the same entity, Sub-Q, Inc. The assignment for Cragg '301 may be found in Reel 9370 Frame 0437 and the assignment for the present invention may be found in Reel 012613 Frame 0797. Accordingly, it is respectfully requested that this rejection be withdrawn.

C. Rejections under 35 U.S.C. §103

1. Standard under 35 U.S.C. §103

According to the Manual of Patent Examining Procedure (M.P.E.P.),

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the applicant's disclosure.[1]

2. Rejections under 35 U.S.C. §103 over Hein et al

Claim 16 stands rejected under 35 U.S.C. 103 (a) as being allegedly unpatentable over Hein and no other prior art reference. This rejection is respectfully traversed.

The office action states:

> "Hein bears a remarkable resemblance to the described subject matter, although it has a different use. See column 1, lines 10-13. Regarding the figures, see especially bleed back channel 10. See also MPEP 2111.02 and the case law therein. The examiner takes the position that the instant claims define a structurally complete invention in the body and the preamble phrase is not accorded much patentable weight. Accordingly, the only different between Hein and the claim invention is the recitation of the size of the bleed back element (less than 2mm). However, it would be obvious to one of ordinary skill in the art to make the bleed back element any size necessary dependent upon patient need in the lack of a showing of criticality. See also MPEP 2144.04 IV.A. and the case law cited therein. It is well established that changes in size are prima facie obvious."

The Examiner merely states that "Hein bears a remarkable resemblance to the described subject matter" and that she "takes the position that the instant claims define a structurally complete invention in the body and the preamble phrase is not accorded much patentable weight"

without any further explanation. There is no clear articulation of which portions of the prior art reference supports the rejection. Thus, Applicant is unsure of how Hein bears any resemblance to the claimed invention. However, Applicant respectfully disagree for the reasons, among others, discussed below.

Amended Claim 16 provides for:

> "A system for determining a location of a blood vessel puncture for delivery of a hemostasis promoting material to the blood vessel puncture to facilitate hemostasis, the system comprising:
>
> **an introducer sheath** having a lumen, a proximal end, and a distal end configured to be inserted into a blood vessel puncture;
>
> **a hemostasis promoting material delivery system** having a connector for forming a fluid tight connection with the proximal end of the introducer sheath; and
>
> a bleed back exhaust tube having a first end in fluid communication with the lumen of the introducer sheath and a second end positioned to deliver blood to an exterior of the system to provide a visual indication of the location of the distal end of the introducer sheath, wherein the bleed back exhaust tube has an inner diameter of less than 2mm."

The claimed invention provides for the delivery of a hemostasis promoting material to a blood vessel puncture site to facilitate hemostasis having an introducer sheath and a hemostasis promoting material delivery system. "A system for delivering hemostasis promoting material of the present invention allows the hemostasis promoting material to be delivered to a blood vessel puncture site by fluid pressure. The system allows the hemostasis promoting material to be delivered through an introducer sheath which is already in place within a tissue tract." (See Specification, ¶ [0045]). "The introducer sheath 10 is an intravascular access sheath as is

[1] M.P.E.P § 2143.

conventionally used for procedures such as coronary angioplasty and stenting procedures." (See Specification, ¶ [0051]).

Hein teaches "a structure by the use of which successive charges of fluid can be injected without removing the needle from the **tissues** and by a continuous operation of the piston. Another object is to provide a plurality of fluid admission channels leading into the syringe barrel and controlled by valves through which fluids to intermix within the barrel may be admitted thereinto and during the outward movement of the piston and ejected into the tissue by an inward movement of the piston." (Col. 1, lines 14-26). Thus, (1) Hein merely teaches the use of a syringe with a needle for injecting fluids into tissue and not at a blood vessel puncture; and (2) Hein does not teach the use of "an introducer sheath . . . [or] a hemostasis promoting material delivery system" as claimed in amended Claim 16.

Accordingly, since Hein does not teach or suggest the portions of the claims and there is no reasonable expectation of success, Applicant believes that a prima facie case of obviousness can not be sustained for the claims over Hein. It is respectfully requested that this rejection be withdrawn.

3. Rejections under 35 U.S.C. §103 over Shaw et al

Claim 16 also stands rejected under 35 U.S.C. 103 (a) as being allegedly unpatentable over Shaw and no other prior art reference. This rejection is respectfully traversed. The office action states:

> "See especially figure 3 and blood indicator 108. Accordingly, the only difference between Shaw and the claimed invention is the recitation of the size of the bleed back element (less than 2mm). However, it would be obvious to one of ordinary skill in the art to make the bleed back element any size necessary dependent upon patient need in the lack of a showing of criticality. See also MPEP 2144.04 IV.A. and the case law cited therein. It is well established that changes in size are prima facie obvious."

The Examiner merely cites "figure 3 and blood indicator 108" as reasons for obviousness without any further explanation. Thus, Applicant respectfully disagree for the reasons, among others, below.

The claimed invention provides for a the delivery of a hemostasis promoting material to a blood vessel puncture site to facilitate hemostasis having an introducer sheath and a hemostasis promoting material delivery system. "A system for delivering hemostasis promoting material of the present invention allows the hemostasis promoting material to be delivered to a blood vessel puncture site by fluid pressure. The system allows the hemostasis promoting material to be delivered through an introducer sheath which is already in place within a tissue tract." (See Specification, ¶ [0045]).

Shaw teaches:

> "a delivery device ... which uses a side port vessel wall locating system, but does not require sliding a hemostatic plug over the catheter body during positioning. The devices allow a one step delivery of a hemostatic material at a desired location in the access channel. The embodiment includes a catheter 88 with a side port 98 to an inner lumen 112, a series of marks 92 indicating depth from the side port, a short annular plug 94 of hemostatic material positioned adjacent the side port, and a protective sheath 90. In FIG 3, the device is configured for entry into the body and positioning using the side port, with the sheath 90 positioned over the plug 94. After the side port is positioned adjacent the vessel wall, the catheter is advanced axially distally the known distance, L_6, from the port to the distal end of the plug, using the marks 92, to accurately position the plug adjacent the wall of the vessel. The sheath is retracted to expose the plug to the access channel.

> The sheath may be retracted so its distal end is adjacent the proximal end of the plug. The catheter can be withdrawn, with the sheath preventing axial distal movement of the plug. The sheath can be removed thereafter."

(Col. 11, lines 66-68 through Col. 12, lines 1-20). Thus, Shaw does not teach the use of "an introducer sheath . . . [or] a hemostasis promoting material delivery system having a **connector** for forming a fluid tight connection with the proximal end of the introducer sheath" as claimed in Claim 16. Rather, Shaw teaches the use of catheter having a hemostatic material positioned adjacent a side port of the catheter. Shaw does not teach the use of a connector to form a fluid tight connection between the introducer sheath and hemostasis promoting material delivery system.

Accordingly, since Shaw does not teach or suggest the portions of the claims and there is no reasonable expectation of success, Applicant believes that a prima facie case of obviousness can not be sustained for the claims over Shaw. It is respectfully requested that this rejection be withdrawn.

D. Dependent Claims

The argument set forth above is equally applicable here. The base claims being allowable, the dependent claims must also be allowable.

In view of the foregoing, it is respectfully asserted that the claims are now in condition for allowance.

Request for Allowance

It is believed that this Amendment places the above-identified patent application into condition for allowance. Early favorable consideration of this Amendment is earnestly solicited.

If, in the opinion of the Examiner, an interview would expedite the prosecution of this application, the Examiner is invited to call the undersigned attorney at the number indicated below.

Respectfully submitted,
THELEN REID & PRIEST LLP

Dated: April 28, 2004

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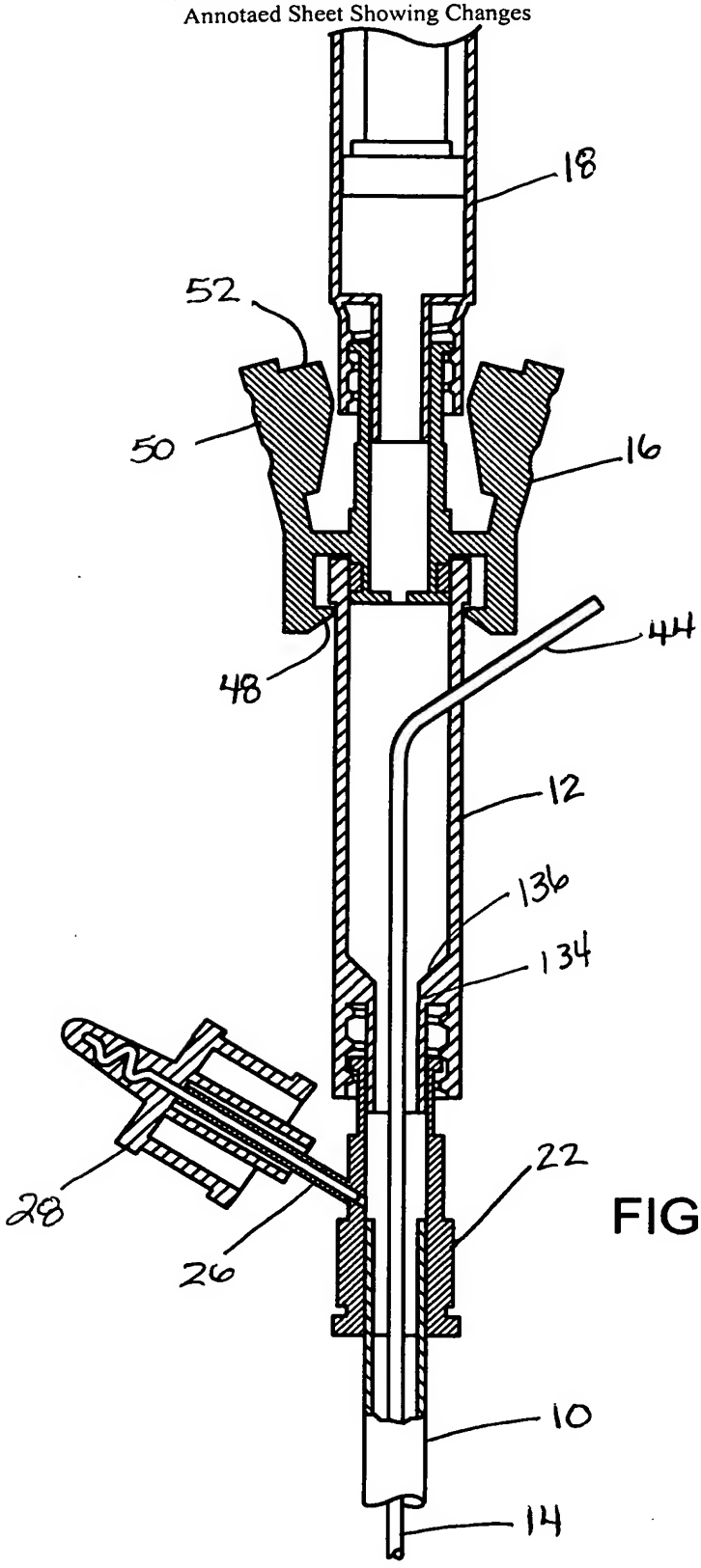

FIG. 3A

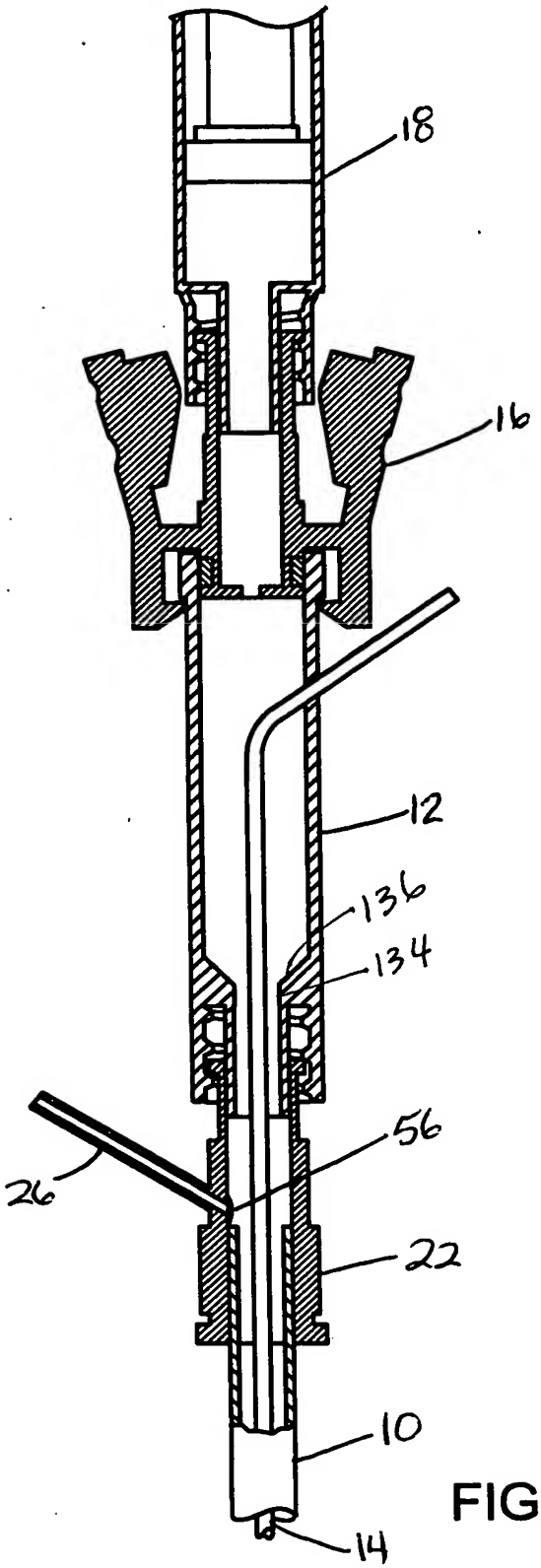

FIG. 3B

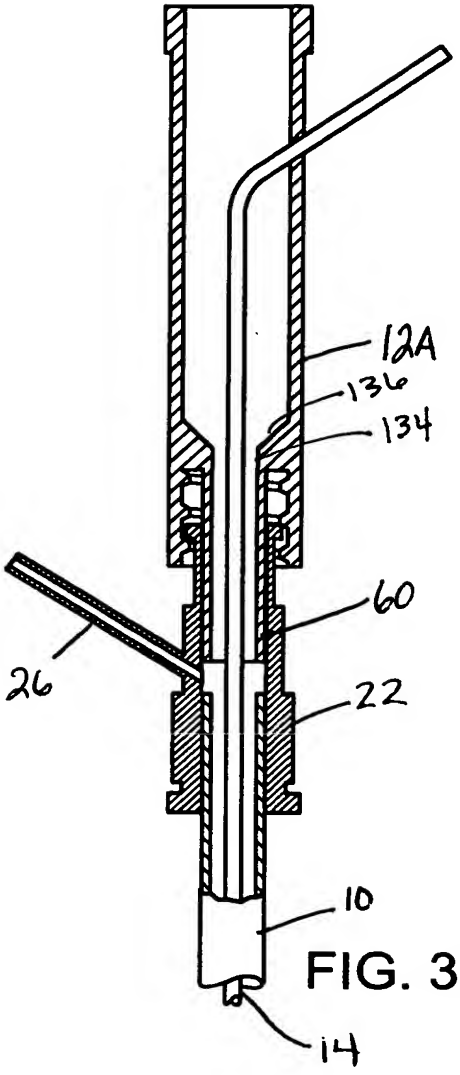

FIG. 3C

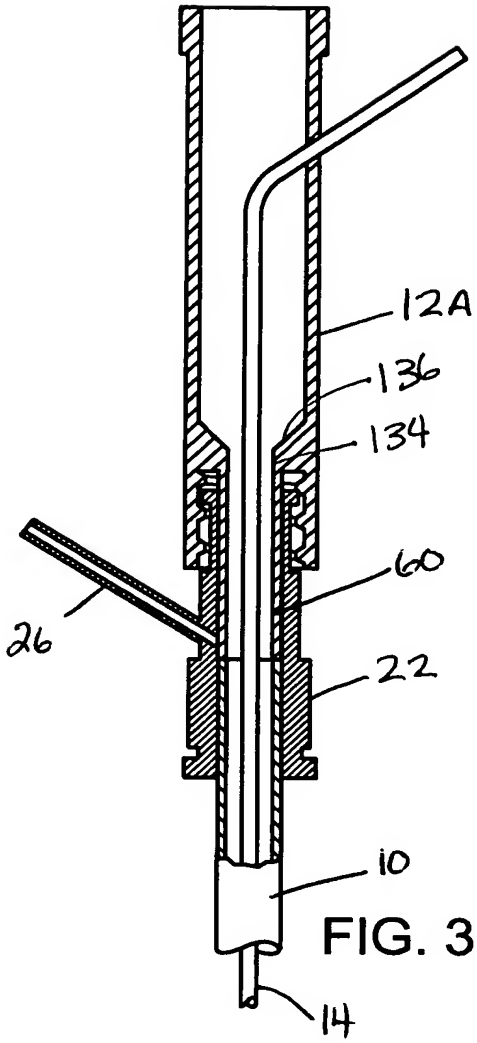

FIG. 3D